



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,117	01/08/2002	Donald F. DePalma	CRD0918	4482

27777 7590 10/19/2004

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,117

Applicant(s)

DEPALMA ET AL.

Examiner

Cheryl Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004 and 22 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/8/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on August 9, 2004 and September 22, 2004 have been entered.

Response to Arguments

Applicant's arguments with respect to claims 1, 5-6, and 19-24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-6, and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites a gasket "maintaining a single flow channel" and also the gasket "including at least one aperture". It is unclear to the examiner how the gasket can have both *a single channel* and *at least one aperture* (the at least one aperture being one or more apertures, creating one or more channels, contradictory to the "single flow channel" claimed above). Claims 5-6 and 19-24 depend upon claim 1 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 19, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Horzewski et al. (US 6,325,823 B1). See figure 4 and respective portions of the specification. Referring to claim 1, Horzewski discloses a system (40) for bypassing an aneurysm (fig.4) comprising a first prosthesis (42), including a conduit having a proximal end (45) and a distal end (46), the conduit establishing a single fluid flow channel, the conduit comprising a stent structure and a graft covering the stent structure (fig.4; col.4, lines 18-22), a compressible gasket (47) positioned inside of the conduit (fig.4; col.5, lines 41-44) and secured to the stent structure around its perimeter thereby maintaining a single flow channel (fig.4), and at least one second prosthesis (41) in fluid communication with the first prosthesis (42) via the distal end (46) of the first prosthesis (42), the gasket (47) including at least one aperture for receiving the at least one second prosthesis (41), the gasket (47) being configured to provide a seal between the first prosthesis and the at least one second prosthesis (col.5, lines 29-33) and to position the at least one second prosthesis (41) within the first prosthesis (42) such that a fluid flow path is established.

Referring to claim 5, Horzewski discloses a gasket (47) *configured* to receive two second prostheses (although only one second prosthesis is shown, gasket 47 is an open ring shape, and is *still capable, or configured*, to receive two prostheses).

Referring to claim 6, Horzewski discloses the at least one second prosthesis (41) to comprise a stent and graft material communicating with the stent (col.4, lines 18-22; fig.4).

Referring to claim 19, Horzewski discloses the gasket (47) to be integrally formed with the graft (graft, col.4, lines 18-22, on prosthesis 42 is attached to gasket 47, see fig.4, and col.5, lines 41-43).

Referring to claim 21, Horzewski discloses the gasket (47) to be substantially impervious to fluid, creating a seal between the first and second prostheses (col.5, line 30-33, 47-49).

Referring to claims 22-24, Horzewski discloses the second prosthesis (41) matingly engaged with the gasket (47) at the distal end (46) of the first prosthesis (42), the first prosthesis having a sufficient length to extend into an aneurysm and the gasket configured to be disposed within the aneurysm (fig.4).

Claims 1, 5, 6, 19, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Ouriel et al. (US 2003/0120333 A1). See figures 1, 10A-10D, and respective portions of the specification. Referring to claim 1, Ouriel discloses a system for bypassing an aneurysm comprising a first prosthesis (140), including a conduit (142) having a proximal end (top) and a distal end (bottom), the conduit (142) establishing a single fluid flow channel (fig.10A), the conduit (142) comprising a stent structure (158) and a graft (157) covering the stent structure, a compressible gasket (156) positioned inside of the conduit and secured to the stent structure

Art Unit: 3738

(158) around its perimeter thereby maintaining a single flow channel (fig. 10A), and at least one second prosthesis (160a-d *or* 160+14) in fluid communication with the first prosthesis (140) via the distal end (bottom) of the first prosthesis, the gasket (156) including at least one aperture (flow channel, fig. 10A) for receiving the at least one second prosthesis (160 or 160+14), the gasket (156) being configured to provide a seal between the first prosthesis (140) and the at least one second prosthesis (160 or 160+14) and to position the at least one second prosthesis within the first prosthesis such that a fluid flow path is established (fig. 10C, 10D).

Referring to claim 5, Ouriel discloses a gasket (156) configured to receive two second prostheses (160a-d or 160+14 a-d; see fig. 10C, 10D).

Referring to claim 6, Ouriel discloses the at least one second prosthesis (160 or 160+14) to comprise a stent (176, 194) and graft material (172, 174, 190, 194) communicating with the stent.

Referring to claim 19, Ouriel discloses the gasket (156) to be integrally formed with the graft (158).

Referring to claim 21, Ouriel discloses the gasket (156) to be substantially impervious to fluid, creating a seal between the first and second prostheses (fig. 10D, [0103]).

Referring to claims 22-24, Ouriel discloses the second prosthesis (160 or 160+14) matingly engaged with the gasket (156) at the distal end (bottom) of the first prosthesis (140, see fig. 10C), the first prosthesis (140) having a sufficient length to extend into an aneurysm and the gasket (156) configured to be disposed within the aneurysm.

Art Unit: 3738

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. (US 6,325,823 B1). Horzewski discloses a system (40) for bypassing an aneurysm substantially as claimed (see above). Horzewski discloses a system (40) comprising first (42) and second (41) prostheses and a gasket (47) connecting the two, the gasket to be made of ePTFE or a closed cell foam material (col.5, lines 43-47), instead of an open cell foam material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a gasket made of an open cell foam, a material well known in the art, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER